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Oleg Shikhman

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EXAMINER

SONNETT, KATHLEEN C

ART UNIT

PAPER NUMBER

3731

NOTIFICATION DATE

DELIVERY MODE

09/15/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

usptopatentmail@cantorcolburn.com

Office Action Summary	Application No. 10/726,031	Applicant(s) SHIKHMAN ET AL.	
	Examiner KATHLEEN SONNETT	Art Unit 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 6/3/2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>6/19/2009</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. **Claims 1, 2, and 9** are rejected under 35 U.S.C. 102(b) as being anticipated by Johnson (U.S. 4,779,616). Johnson discloses a suture loading assembly for threading suture material through a surgical instrument, the suture loading assembly comprising a body (10), an attaching member (12) extending from the body and a flexible loop (14) extending from a distal end of the body. Regarding the attaching member, the language “for attaching the body to the surgical instrument” is considered functional language and the attaching member must only be capable of being used to attach to a surgical instrument. Depending on the structure of the surgical instrument, the member can be attached by a clip member that extends from the surgical instrument and engages the attaching member (12). It is noted that the surgical instrument appears only in functional language and therefore any surgical instrument can be chosen. The body includes a bore from which the wire loop extends.

3. **Claims 1-5 and 9** are rejected under 35 U.S.C. 102(b) as being anticipated by Grossi et al. (U.S. 4,917,082; “Grossi”). Grossi discloses a suture loading assembly for threading suture material through a surgical instrument, the suture loading assembly comprising a body (62), an attaching member (68,70) extending from the body and a flexible loop (22) extending from a distal end of the body (see fig. 1-4). Regarding the attaching member, the language “for attaching the body to the surgical instrument” is considered functional language and the

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attaching member must only be capable of being used to attach to a surgical instrument. The body includes a bore from which the wire loop extends (col. 4 ll. 58-62).

4. Regarding claims 3 and 4, the attaching member includes two legs extending from the body, an inner portion of each leg curved to accept a cylindrical member of a surgical instrument wherein the attaching member is slidable along the cylindrical member of the surgical instrument (see fig. 1 and 3). The outer portion of each leg includes an indented area where it joins to body (62). This can be used as a finger grip if one where to grab the device at this point.

5. Regarding claim 5, the body is now being considered element (60) and the cap is being considered portion (62), which surrounds element (60). The attaching member is still elements (68,70) which extend from body (60) since body (60) is within cap (62).

6. **Claims 1, 2, and 5-9** are rejected under 35 U.S.C. 102(b) as being anticipated by Riza (U.S. 5,501,692). Riza discloses a suture loading assembly for threading suture material through a surgical instrument, the suture loading assembly comprising a body (30), an attaching member (20) extending from the body and a flexible loop (36) extending from a distal end of the body. Regarding the attaching member, the language “for attaching the body to the surgical instrument” is considered functional language and the attaching member must only be capable of being used to attach to a surgical instrument. Depending on the structure of the surgical instrument, the member can be attached by a clip member that extends from the surgical instrument and engages the attaching member (20) at its proximal-most end (21). The body includes a bore from which the wire loop extends.

7. Regarding claims 5-7, the device includes a cap (11) surrounding a portion of the body (see fig. 4). The cap includes indents in the sides of the cap that serve as finger grips. Portions (12) and (13) are being considered the base line and the remaining portions of cap (11) are indented from this base line. These can serve as finger grips.

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8. Regarding claim 8, the cap includes openings for receiving the body and the attaching member (see fig. 4).

9. **Claims 1, 9, 11-13, and 20** are rejected under 35 U.S.C. 102(b) as being anticipated by Ek (U.S. 5,935,149). Regarding claims 11-13 and 20, Ek discloses a suture securing instrument comprising an elongated tubular portion having a distal and proximal end, the distal end including a ferrule (212) accepting opening (see fig. 10) the proximal end attached to a handle assembly (see fig. 12) and a suture loading assembly in combination with the instrument comprising a body (400), an attaching member (402) extending from the body for attaching the body to an exterior portion of the elongated tubular portion of the suture securing instrument (fig. 12, col. 5, ll. 63-67) and a flexible loop (410) extending from a distal end of the body. If the surgical instrument were held such that the attaching member is above the suture securing instrument, the attaching member (402) is larger than aperture (62) and will sit on top of the elongated tubular portion and won't be able to fall through the aperture due to its size, and therefore can be considered attached to an exterior of the instrument. The loop is threaded through the ferrule accepting opening (see fig. 10) and loop (410) is made of wire bent into a diamond shape. In a first position, the flexible loop is provided through an opening in a ferrule (212) and in a second position is provided at least partially retracted from the ferrule and the suture material is at least partially provided within the ferrule (fig. 13, 13a).

10. Regarding claims 1 and 9, Ek discloses a suture loading assembly comprising a body (400), an attaching member (402) that is capable of being attached to an exterior portion of the surgical instrument, and a flexible loop (410) made from wire extending from a distal end of the body.

11. Regarding claim 13, the attaching member (402) is capable of being slid along the tubular portion of the suture securing instrument. In other words, there is nothing that would stop

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a user from being able to hold the attaching member (402) and slide it along the suture securing instrument.

12. **Claims 1, 11-13, 18, and 19** are rejected under 35 U.S.C. 102(b) as being anticipated by Sauer et al. (U.S. 5,520,702; "Sauer '702"). Sauer '702 discloses a suture securing instrument comprising an elongated tubular portion having a distal and proximal end, the distal end including a ferrule accepting opening (62), the proximal end attached to a handle assembly and a suture loading assembly (304) in combination with the instrument, the suture loading assembly comprising a body (straight portion extending from loop 304), an attaching member (rounded proximal portion) extending from the body for attaching the body to the elongated tubular portion of the suture securing instrument, and a flexible loop extending from a distal end of the body. If the device were held such that the attaching member is above the suture securing instrument, the attaching member is larger than aperture (62) and will just sit on top of the elongated tubular portion. As mentioned above, the language "for attaching the body to the surgical instrument" is considered functional language and the attaching member must only be capable of being used to attach to a surgical instrument. A third piece that clips onto both the elongated tubular member and the attaching member could be used to mount the attaching member to the elongated tubular member. In a first position, the flexible loop is provided through an opening in a ferrule (100) and in a second position is provided at least partially retracted from the ferrule and the suture material is at least partially provided within the ferrule (fig. 4 and 5).

13. Regarding claim 12, the loop is threaded through the ferrule accepting opening (fig. 4, 5).

14. Regarding claim 13, it is possible to slide the attaching member along the tubular portion of the securing instrument, for example, after the loop (304) has been removed from the ferrule

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(100) since there is no structure on the attaching member or the tubular portion that would prevent this.

15. Regarding claim 18, the suture-securing instrument comprises an aperture in the elongated tubular portion, the aperture located proximally of the ferrule-accepting opening, the flexible loop threaded through the aperture prior to threading through the ferrule-accepting opening. The ferrule is placed at an angle as seen in Fig. 3 and therefore, aperture (76) is proximal to the ferrule opening.

16. Regarding 19, a ferrule is positioned in the ferrule accepting opening.

Claim Rejections - 35 USC § 103

17. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

18. **Claim 10** is rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson.

Johnson discloses the invention substantially as stated above but does not expressly disclose a plug used to retain the wire within the body but instead discloses swaging the wire within the body to hold the wire in place (see col. 2 lines 23-26). At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to use a plug to retain the wire within the body because Applicant has not disclosed that the use of such a plug provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected the modified device of Johnson and applicant's invention to perform equally well with either the claimed plug or the

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swaging taught by Johnson because both perform the same function of connecting the wire loop to the body. Therefore, it would have been prima facie obvious to further modify Johnson to obtain the invention as specified in claim 10 because such a modification would have been considered a mere design consideration which fails to patentably distinguish over the prior art of modified Johnson.

19. **Claims 16 and 17** are rejected under 35 U.S.C. 103(a) as being unpatentable over Sauer '702 in view of Samoilov (US 4,102,478). Sauer '702 discloses the invention substantially as stated above including a suture loading assembly comprising a body, attaching member, and wire loop (fig. 4; 304) but fails to disclose a cap surrounding the body and attaching member, the cap extending past the tubular portion. Sauer '702 does not expressly disclose how the body and attaching member are attached to one another. Samoilov teaches an attachment between a wire member and an attaching member formed by crimping the wire between the attaching member (12) and a cap member (5) that surrounds the wire (near 25) and the attaching member (see fig. 1). It would have been obvious to one skilled in the art to use such an attachment between the body and attaching member of Sauer '702 because one skilled in the art has good reason to pursue known attachments between a body and attaching member within her or her technical grasp. If this leads to the anticipated success, it is likely the product of ordinary skill. Regarding claim 17, indentations forming finger grips on the area of an instrument engaged by a hand are very well known in the art and would have been an obvious modification to enhance user control over operation of the instrument.

20. **Claims 14, 15, and 21-25** are rejected under 35 U.S.C. 103(a) as being unpatentable over Sauer '702 in view of Sauer (U.S. 5,643,289; "Sauer '289") and Iglesias (U.S. 4,134,406). Sauer '702 discloses a suture securing instrument as discussed in more detail above but fails to disclose an attaching member that is slidable along the tubular portion of the suture securing

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instrument and includes two legs extending from the body. Sauer '702 fails to disclose an attaching member that includes two legs extending from the body.

21. However, Sauer '289 discloses that threading tools can be modified so that the threading can be accomplished intracorporeally (see col. 7, ll. 17-21). Iglesias discloses that it is old and well known to mount one medical device to another when the devices are used in conjunction with one another. In particular, Iglesias discloses mounting a wire loop (28) onto another medical device (10), with which it is used in conjunction. In the device of Iglesias, there is an attaching member (40) that extends from the body (22) of the device. Such an arrangement allows the loop to be inserted and removed easily in a very small space (intracorporeally). This is advantageous in endoscopic procedures since space at the surgical site is generally limited. Sauer '702 discloses the use of a suture loading assembly comprising a loop to pull suture proximally along the tubular portion of the suture-securing instrument (see fig. 4, 5, and 7) and Sauer '289 teaches that the threading tool can be modified so that the threading can be accomplished intracorporeally. Using the teachings of Iglesias, it would have been obvious to one skilled in the art to modify the device of Sauer '702 to include an attaching member that includes two legs extending from the body in order to modify the threading assembly as suggested by Sauer '289 to gain the advantage of providing a threading assembly that can thread intracorporeally.

22. Regarding claims 14-15, the attaching member taught by Iglesias is slidable along the tubular portion of the suturing securing instrument (col. 3 ll. 10-14). The attaching member includes two legs extending from the body, an inner portion of each leg curved to accept the tubular portion of the suture-securing instrument. As seen in fig. 2, the legs have an indented area near their base (where 22 slides into the attaching member) and this can be used as a finger grip.

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23. Regarding claim 25, Sauer '702 discloses that the device may include a cutting blade.

24. Regarding claims 21-25, Sauer '702 discloses the method of threading a suture securing instrument comprising threading a flexible loop extending from the suture loading assembly through a ferrule within a distal end of the suture loading assembly, inserting suture material through the flexible loop (304) and pulling the flexible loop proximally until the suture material is threaded through the ferrule (see fig. 4 and 5). The suture loading assembly has a body as seen in fig. 4 but does not include an attaching member that extends from the body to mount the assembly to the body of the suturing device. Sauer '702 fails to disclose mounting a suture loading assembly upon a tubular portion of the suture-securing instrument and sliding the suture loading assembly proximally along the tubular portion of the securing instrument.

25. As discussed above, Sauer '289 discloses that threading tools can be modified so that the threading can be accomplished intracorporeally (see col. 7, ll. 17-21). Iglesias discloses mounting a wire loop to a medical device when the devices are used in conjunction with one another. Such an arrangement allows the loop to be inserted and removed easily in a very small space (intracorporeally). Using the teachings of Iglesias, it would be obvious to one of ordinary skill in the art to modify the method of Sauer et al. to include mounting the suture loading assembly onto the tubular portion of the suture securing instrument through an attaching member that extends from the body of the suture threading assembly in order to modify the threading assembly as suggested by Sauer '289 to gain the advantage of providing a threading assembly that can thread intracorporeally.

Response to Arguments

26. Applicant's arguments filed 6/3/2009 have been fully considered but they are not persuasive. Applicant argues that Johnson and Riza do not teach attachment members for attaching the body of the device on an exterior portion of a surgical instrument. However, it is

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noted that the surgical instrument appears only in functional language in claim 1 and therefore the suture loading assembly must only be capable of attaching to any surgical instrument. . A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. That is to say, the claim is drawn only to the suture loading assembly and not to the surgical instrument; the surgical instrument is not being claimed as an element of the suture loading assembly. Rather, the suture loading assembly must be capable of threading suture material through a surgical instrument. A surgical instrument can be chosen which includes two legs on its outside surface that can grip the handle (12) of Johnson or the handle (20) of Riza. In this case, the handles of these devices can be considered an attaching member since they are used to attach the body to the surgical instrument. Because the surgical instrument occurs only in functional language ("for threading suture material through a surgical instrument"; "for attaching the body of an exterior portion of the surgical instrument"), the body, attaching member, and flexible loop must only be capable of interacting with an opening in the body of any surgical instrument in the manner claimed. The preamble has been considered and the examiner maintains the position that the preamble is limiting in so far as the suture loading assembly must be capable of threading suture material through a surgical instrument.

27. Regarding Grossi, applicant argues that Grossi fails to disclose a flexible loop. However, Grossi discloses that the wire (14) is flexible and the sleeves that add stiffness to the wire (14) do not cover loop portion (col. 4, ll. 41; fig. 2). "Suture material" appears in the claim but the "suture material" is not being claimed as part of the device (i.e. it is not positively recited). It appears only in functional language in claim 1 and therefore the suture loading assembly must only be capable of threading suture material through a surgical instrument. A recitation of the

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intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

28. Claim 11 claims a suture securing instrument (elongated tubular portion) to which the attaching member on the suture loading assembly is attached. The prior art must now include the suture securing instrument. However, the attaching member is claimed as "for attaching the body on an exterior portion of elongated tubular portion of the suture securing instrument" and not claimed as being attached to the elongated tubular portion. This is considered functional language and the attaching member must only be capable of being attached to the elongated tubular portion.

29. Regarding the prior art of Ek, applicant argues that ring (402) cannot be considered an attaching member extending from the body for attaching the body on an exterior position of the elongated tubular portion of the suture securing instrument. However, as discussed above, if the device were held such that the attaching member is above the suture securing instrument, the attaching member is larger than aperture (62) and will just sit on top of the elongated tubular portion. As mentioned above, the language "for attaching the body to the surgical instrument" is considered functional language and the attaching member must only be capable of being used to attach to a surgical instrument. A third piece that clips onto both the elongated tubular member and the attaching member could be used to mount the attaching member to the elongated tubular member. This is also true for the device of Sauer '702. Applicant argues that clipping the attaching member and the instrument is not disclosed by Sauer '702. The examiner agrees. However, claim 11 is an apparatus claim and includes only that the attaching member is capable of attaching the body on an exterior portion of another instrument. Thus the prior art

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must only have an attaching member that is capable of being attached in any way to an exterior portion of the suture securing instrument in order to anticipate the claim.

30. Regarding the combination of Sauer '702 in view of Sauer '289 and Iglesias, applicant argues that Iglesias merely teaching that two components used together can be attached does not make obvious applying such a teaching to the device of Sauer. The examiner respectfully disagrees. Sauer '702 in view of Sauer '289 discloses a surgical instrument that has a threading tool modified so that threading can be accomplished intracorporeally. Iglesias teaches a surgical device that attaches two instruments together, one instrument being a wire loop, such that they can slide relative to one another in a very controlled manner since one piece cannot migrate around the other due to the attachment mechanism. One skilled in the art would have been motivated to further modify Sauer to include attaching the suture loading assembly upon the suture-securing instrument in view of the teachings of Iglesias in order to more finely control the relative sliding of the two instruments in a small space. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

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MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KATHLEEN SONNETT whose telephone number is (571)272-5576. The examiner can normally be reached on 7:30-5:00, M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KCS 9/4/2009

/Anhtuan T. Nguyen/
Supervisory Patent Examiner, Art Unit 3731
9/10/09